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EXAMINER

OROPEZA, FRANCES P

ART UNIT	PAPER NUMBER
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3762

DATE MAILED: 05/12/2003

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Please find below and/or attached an Office communication concerning this application or proceeding.

# Office Action Summary

Application No.

09/976,799

Applicant(s)

GREENBERG ET AL. 

Examiner

Frances P. Oropeza

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

## Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

## Status

- 1) ☒ Responsive to communication(s) filed on 10/21/01 (Filing & Prel. Amend.).
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

## Disposition of Claims

- 4) ☒ Claim(s) 269-309 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 269-302 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☒ Claim(s) 303-309 are subject to restriction and/or election requirement.

## Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 October 2001 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on \_\_\_\_\_ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

## Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some \* c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.
- 14) ☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

## Attachment(s)

- 1) ☒ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☒ Information Disclosure Statement(s) (PTO-1449) Paper No(s) 3.
- 4) ☒ Interview Summary (PTO-413) Paper No(s) 4.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

**DETAILED ACTION**

***Election/Restrictions***

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:
  - I. Claims 269-302, drawn to a visual prosthetic, classified in class 607, subclass 54.
  - II. Claims 303-308, drawn to an implantable device comprising a ceramic substrate, feed throughs and active electronics, classified in class 607, subclass 53.
  - III. Claim 303, drawn to an implantable device comprising a substrate with feed throughs, a plurality of capacitors electrically coupled to the feed throughs and active electronics coupled to the capacitors, classified in class 607, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

Inventions I. and II. are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I. has separate utility such as a visual prosthetic not requiring a ceramic substrate with feed throughs. See MPEP § 806.05(d).

Inventions I. and III. are related as subcombinations disclosed as usable together in a single combination. The subcombinations are distinct from each other if they are shown to be separately usable. In the instant case, invention I. has separate utility such as a visual prosthetic not requiring a plurality of capacitors. See MPEP § 806.05(d).

Inventions II. and III. are related as combination and subcombination. Inventions in this relationship are distinct if it can be shown that (1) the combination as claimed does not require the particulars of the subcombination as claimed for patentability, and (2) that the subcombination has utility by itself or in other combinations (MPEP § 806.05(c)). In the instant case, the combination as claimed does not require the particulars of the subcombination as claimed because the combination does not require the plurality of capacitors. The subcombination has separate utility such as an implantable device not requiring the active electronics to be electrically coupled to the feed throughs but rather the active electronics electrically coupled to the plurality of capacitors and the capacitors electrically coupled to the feed throughs.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

During a telephone conversation between Scott B. Dunbar and Frances P. Oropeza on 4/29/03, a provisional election was made without traverse to prosecute the invention of Group I., claims 269-302. Affirmation of this election must be made by applicant in replying to this Office action. Claims 303-309 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

The Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim

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remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

***Claim Rejections - 35 USC § 101***

2. 35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 269-302 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Specifically, "unit, implanted within a living body" (claims 269 and 289), "unit stimulating visual neurons" (claim 269), "electrodes stimulating a retina" (claim 283 and 289), "electrodes positioned within a vitreous humor" (claim 283), and "device is positioned in the center of the vitreous humor" (claim 284), amount to inferential recitation of the body, which renders these claim non-statutory. A phrases such as --unit, adapted to be implanted within a living body-- and --unit for stimulating visual neurons-- are suggested to address the understood intent of the Applicant and avoid the 35 U.S.C. 101 rejection. Appropriate correction is required.

***Claim Rejections - 35 USC § 112***

3. The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 273, 274, 293 and 294 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter that was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or

use the invention. The Examiner is unable to find reference to and description of the feed throughs (claims 273 and 293) or the metal ring or metal lid (claims 274 and 294) in the specification or in any figure, hence the Examiner is unable to provide prior art against these elements because these elements are not disclosed in sufficient detail.

4. The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claim 272, 273, 274, 282, 290, 292, 293, 294 and 302 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

The scope of claims 272-274, 282, 292-294 and 302 are indefinite because the limitation in the claims refers to the method of making rather than the resultant apparatus.

Claims 273 and 293 are unclear because the relationship between the feed throughs and a ceramic portion is not precisely defined. Lacking a description in the specification and a figure, the Examiner is unable to understand the relationship of the elements and potentially find prior art teaching the Applicant's invention. As a general statement, feed throughs are well known in the implantable stimulation device art to enable a connection between the electrodes and the implanted electronics.

Claims 273 and 293 are indefinite because the Examiner is unclear what "a ceramic portion" is associated with - possibly the hermetic package of claim 269.

Claims 274 and 294 are unclear because the relationships between the ring, lid and hermetic box are not precisely defined. Lacking a description in the specification

and a figure, the Examiner is unable to understand the relationship of the elements and potentially find prior art teaching the Applicant's invention.

Claim 290 is a duplicate of claim 270; it appears claim 290 should depend on claim 289 and not claim 269.

Appropriate correction is required.

***Claim Rejections - 35 USC § 102***

5. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

6. Claims 269, 270, 275, 276, 283, 284, 285, 289, 290 and 296 are rejected under 35 U.S.C. 102(b) as being anticipated by de Juan, Jr. et al. (US 5109844). De Juan, Jr. et al. disclose a retinal micro-stimulator. The thin film/ hermetic box is read to be the low temperature surface oxide deposition formed over the silicon wafer and electronics (figure 7; col. 4 @ 66 – col. 5 @ 36). Based on figure 7, the visual prosthetic is centered in the vitreous humor.

***Claim Rejections - 35 USC § 103***

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint Inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the Examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. The Applicant is advised of the obligation under 37 CFR 1.56 to point out the Inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

8. Claims 271, 278-281, 287, 288, 291 and 297-301 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Juan, Jr. et al. (US 5109844) in view of Schulman et al. (US 6259937). As discussed in paragraph 6 of this action, de Juan, Jr. et al. disclose the claimed invention except for the hermetic box being metal and ceramic (claims 271 and 291), and the thin film being a coating of aluminum oxide (claims 278, 287, and 298), zirconium oxide (claims 279, 288 and 299), tantalum (claims 280 and 300) or silicon oxide/ nitride /carbide (claims 281 and 301).

Schulman et al. teach implantable device coatings using: a combination of metal and ceramic (col. 9 @ 62-64; col. 10 @ 48-51), and the thin film being a coating of aluminum oxide (col. 3 @ 11-13; col. 7 @ 39-48), zirconium oxide (col. 3 @ 11-13; col. 7 @ 39-48), tantalum oxide (col. 7 @ 39-48) or silicon oxide (col. 7 @ 39-48) for the purpose of providing an effectively hermetic seal to protect the feed throughs and other portions of the device from damage when exposed to bodily fluids (col. 7 @ 7-19).



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It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the proven barriers that are a combination of metal and ceramic, and thin film being made of aluminum oxide, zirconium oxide, tantalum oxide, or silicon oxide in the de Juan, Jr. et al. system in order to avoid damaging the device components and making the device inoperable (col. 2 @ 9-14).

9. Claims 277, 280, 281, 287, 297, 300 and 301 are rejected under 35 U.S.C. 103(a) as being unpatentable over de Juan, Jr. et al. (US 5109844) in view of Davidson (US 5683442). As discussed in paragraph 6 of this action, de Juan, Jr. et al. discloses the claimed invention except for the film being a diamond/ diamond-like coating (claims 277, 286 and 297), tantalum (claims 280 and 300), or silicon oxide/ nitride/ carbide (claims 281 and 301).

Davidson teaches coatings on body implants using a film that is a diamond/ diamond-like coating (col. 3 @ 46-56), tantalum (col. 2 @ 26-32), or silicon oxide/ nitride/ carbide coating (col. 5 @ 24-28) for the purpose of providing a toxin free material that is wear resistant and hemocompatible as a material of construction for the body implant. It would have been obvious to one having ordinary skill in the art at the time of the invention to have used the proven films of a diamond/ diamond-like coating, tantalum, or silicon oxide/ nitride/ carbide coating in the de Juan, Jr. et al. system in order to avoid blood clots caused by non optimum materials and and to avoid catastrophic failure of the implanted device (col. 1 @ 21-27 and 59-61; col. 2 @ 3-10 and 35-39).

***Drawings***

10. The drawings are objected to because:

The labels in the rectangles of figure 1b do not correspond with the elements defined in the specification on page 14 starting at line 30, page 15 starting at line 4, page 18 starting at line 33 and page 19 starting at lines 13 and 24. Common nomenclature is required between the specification and the figures.

The Examiner is unable to find the reference numeral (20), (103) and (119) of figure 1b in the specification.

In figure 2a it appears "C202" should be --202--.

In the paragraph of the specification discussing figure 3a (page 19, starting at line 24), multiple descriptions are used with the same reference numerals. Common nomenclature is required between the specification and the figures. In the same paragraph, reference numeral 321 is given two descriptions. Clarification is needed.

The reference numeral "121" is used to describe different elements in figure 1b and in figure 3c and 3d.

Figures 4 and 5 are objected to under 37 CFR 1.83(a) because the rectangular/triangular boxes are not labelled as described in the specification. Any structural detail that is essential for a proper understanding of the disclosed invention should be shown in the drawing. MPEP § 608.02(d). A proposed drawing correction or corrected drawings are required in reply to the Office action to avoid abandonment of the application. The objection to the drawings will not be held in abeyance.

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According to the specification figure 6c should contain two positive and one negative electrodes (specification – page 21, lines 26-28). The figure contains one positive and two negative electrodes.

Figure 8c is unclear because it appears reference numeral (817) should be (820) (instant specification – page 22, lines 14-17 and page 24, line 1).

Figure 12c uses reference numeral (1207) but the Examiner is unable to find (1207) in the specification (specification – page 26, second paragraph).

The specification discloses electrodes/ array (1201), but this reference numeral is not found in figure 12d (specification – page 26, lines 10 and 17).

The specification discloses controls (2001, 2002, 2003), but these reference numerals are not found in figure 20 (specification – page 32, third paragraph).

Correction is required.

### ***Specification***

11. The specification is objected to because:

The specification lacks a brief description for figures 19A, 19b and 19c.

The specification references figure "8" (page 24, line 6), but there is no figure 8.

The specification on page 25, first paragraph associates reference numeral (1103) with three different elements. Clarification is needed.

The specification is unclear because on page 26, line 18, it appears (1202) should be deleted.

The specification is unclear because on page 26, line 27, it appears "12c" should be --12d--.

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The specification is unclear because on page 27, line 21, it appears (1302) should be deleted.

The specification on page 27, second paragraph associates reference numeral (1306) with two different elements. Clarification is needed.

Figure 16a and 16b are unclear because the specification, on page 28, final paragraph and on page 29, first paragraph, does not define the elements 1601-1605, 1610 and 1611) shown in the figures.

Appropriate correction is required.

### **Conclusion**

Any inquiry concerning this communication or earlier communications from the Examiner should be directed to Fran Oropeza, telephone number is (703) 605-4355.

The Examiner can normally be reached on Monday – Thursday from 6 a.m. to 4:30 p.m.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's Supervisor, Angela D. Sykes can be reached on (703) 308-5181. The fax phone number for the organization where this application or proceeding is assigned is (703) 306-4520 for regular communication and for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Receptionist, telephone number is (703) 308-0858.

Frances P. Oropeza  
Patent Examiner  
Art Unit 3762

380  
5/1/03



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